Review 2012: Contraceptives (Combined oral)

Oral contraceptives containing Drospirenone for premenstrual syndrome

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Objective: To review all randomized controlled trials comparing a combined oral contraceptive containing drospirenone to a placebo or another combined oral contraceptive for the effect on premenstrual symptoms.

Number of studies and types of papers: We included 5 trials with a total of 1920 women.

Databases searched: We searched for studies of drospirenone and premenstrual syndrome in the following databases: Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library), MEDLINE, and POPLINE (20 Dec 2011); EMBASE, LILACS, PsycINFO, ClinicalTrials.gov, and the International Clinical Trials Registry Platform (ICTRP) of the World Health Organization (02 Mar 2011). We also examined references lists of relevant articles and wrote to known investigators to find other trials.

Inclusion criteria: We included randomized controlled trials in any language that compared a combined oral contraceptive (COC) containing drospirenone with a placebo or with another COC for the effect on premenstrual symptoms. The primary outcome included affective and physical premenstrual symptoms that were prospectively recorded. Adverse events related to combined oral contraceptive use were examined.

Methods for assessing research quality: Two review authors independently extracted data and assessed study quality.

Statistical analysis methods: For continuous variables, the mean difference (MD) was computed with 95% confidence interval (CI). For dichotomous outcomes, the Peto odds ratio (OR) with 95% CI was calculated.

Efficacy outcomes: Two placebo-controlled trials of women with PMDD showed less severe premenstrual symptoms after three months with drospirenone 3 mg plus ethinyl estradiol 20 µg than with placebo (MD -7.92; 95% CI -11.16 to -4.67). The drospirenone group had greater mean decreases in impairment of productivity (MD -0.31; 95% CI -0.55 to -0.08), social activities (MD -0.29; 95% CI -0.54 to -0.04), and relationships (MD -0.30; 95% CI -0.54 to -0.06).

Three trials studied the effect of drospirenone 3 mg plus ethinyl estradiol 30 µg on less severe symptoms. A placebo-controlled six-month trial had insufficient data for primary outcome analysis. Another six-month study used levonorgestrel 150 µg plus ethinyl estradiol 30 µg for the comparison group but did not provide enough data on premenstrual symptoms. In a two-year trial, the drospirenone COC group had similar premenstrual symptoms to the comparison group given desogestrel 150 µg plus ethinyl estradiol 30 µg (OR 0.87; 95% CI 0.63 to 1.22).

Side-effects assessment: In two placebo-controlled trials of women with PMDD, the side effects more common with the use of the drospirenone COC contraceptive were nausea, intermenstrual bleeding, and breast pain. The respective odds ratios were 3.15 (95% CI 1.90 to 5.22), 4.92 (95% CI 3.03 to 7.96), and 2.67 (95% CI 1.50 to 4.78). Total adverse events related to the study drug were more likely for the drospirenone COC group (OR 2.36; 95% CI 1.62 to 3.44).

Three trials studied the effect of drospirenone 3 mg plus ethinyl estradiol 30 µg on less severe symptoms. The groups were also similar for adverse events related to treatment (OR 1.02; 95% CI 0.78 to 1.33).

Conclusion: Drospirenone 3 mg plus ethinyl estradiol 20 µg may help treat premenstrual symptoms in women with severe symptoms, that is, premenstrual dysphoric disorder. The placebo also had a large effect.

Considerations for future: We do not know whether the combined oral contraceptive works after three cycles, helps women with less severe symptoms, or is better than other oral contraceptives. Larger and longer trials of higher quality are needed to address these issues. Trials should follow CONSORT guidelines.